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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,545	11/14/2008	Giles Albert Brown	13425-192US1 BV-1087 US	3942
26161 7590 04/06/2011 FISH & RICHARDSON P.C. (BO) P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER CRANE, LAWRENCE E	
			ART UNIT 1623	PAPER NUMBER
			NOTIFICATION DATE 04/06/2011	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,545	<b>Applicant(s)</b> BROWN ET AL.	
	<b>Examiner</b> Lawrence E. Crane	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on March 25, 2011 (RCE & amendment).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14 and 40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 is/are allowed.
- 6) ☒ Claim(s) 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Claim **15-17, 36 and 39** were previously cancelled, claims **1-13, 18-35, 37, 38 and 41-44** have been newly cancelled, no claims have been amended, the disclosure has not been further amended, the Abstract has been further amended, and no new claims have been added as per the Request for Continued Examination (RCE) and the amendment filed March 25, 2011. No additional or supplemental Information Disclosure Statements (0 IDSs) have been filed as of the date of this Office action.

Claims **14 and 40** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line **y**, the line number “y” is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claim **40** is rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Factors to be considered in this analysis:

a) Actual Reduction to Practice: A page-by-page inspection of the entire disclosure indicates that applicant has asserted at page a greater than 96% purity for 2-methoxyadenosine (spongiosine), but examiner was unable to locate any experimental basis for this claimed limitation, including any chromatographic analyses or other variety of quantitative data in the description of the synthesis of spongiosine at page 19 of the disclosure. Also examiner does not find any comparative data wherein competent comparisons have been made with the reports of spongiosine synthesis, isolation, and characterization by **Bergmann et al.** (PTO-1449 ref. **AC**; see page 1576 at column 2, wherein a successful mixed melting point test and closely corresponding elemental analytical data are disclosed) or **Ojha et al.** (PTO-1449 ref. **AI**; see the synthesis of spongiosine with an 87% yield, and a listing of melting point data, NMR data, and appropriate CHN analysis data, are disclosed at page 1897, lines 1-11). In the absence of a credible showing that applicant has synthesized spongiosine with a purity equal to or greater than that disclosed by any one of **Bergmann et al.**, **Ojha et al.**, or even **Schaefer et al.** (PTO-1449 ref. **AL**; see page 3741, column 2, synthesis of compound VIII), examiner remains

unconvinced that the instant written description adequately supports an assertion that 2-methoxyadenosine with a purity of greater than 96% has been isolated by applicant.

b) Disclosure of Drawings, Structural, and Other Chemical Formulas: This factor is not applicable in the instant analysis.

c) Sufficient relevant identifying characteristics? This factor is not applicable in the instant analysis.

d) Method of making the claimed invention? This factor is dealt with in the first paragraph of this analysis above.

e) Level of skill in the art? This factor is not applicable in the instant analysis.

f) Predictability in the art? This factor is not applicable in the instant analysis.

Therefore, there remains a serious question concerning whether the instant assertion of a purity of instant-isolated 2-methoxyadenosine of greater than 96% is credible in light of the absence of any quantitative data in support thereof in the instant file history.

Applicant's arguments with respect to claim **40** have been considered but are moot in view of the new grounds of rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

(f) he did not himself invent the subject matter sought to be patented."

Claim **40** is rejected under 35 U.S.C. §102(b) as being anticipated by **Bergmann et al.** (PTO-1449 ref. **AC**).

Applicant is referred to the **Bergmann et al.** reference at page 1576 at column 2, wherein a successful mixed melting point test and closely corresponding elemental analytical data are disclosed which clearly establish that **Bergmann et al.** had synthesized authentic spongine, aka 2-methoxyadenosine. Therefore, the disclosures of the noted reference have been found to have anticipated the subject matter of the noted claim.

Applicant's arguments with respect to claim **40** have been considered but are moot in view of the new grounds of rejection.

Claim **40** is rejected under 35 U.S.C. §102(b) as being anticipated by **Ojha et al.** (PTO-1449 ref. **AI**).

Applicant is referred to the **Ojha et al.** reference wherein the synthesis of spongine, aka 2-methoxyadenosine, with an 87% yield, and a listing of melting point data, NMR data, and appropriate CHN analysis data, are disclosed at page 1897, lines 1-11. Therefore, the disclosures of the noted reference have been found to have anticipated the subject matter of the noted claim. ,

Applicant's arguments with respect to claim **40** have been considered but are moot in view of the new grounds of rejection.

Claim **14** is allowable as submitted.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < <http://pair-direct.uspto.gov> >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec  
**03/26/2011**

/Lawrence E. Crane/

Primary Examiner, Art Unit 1623

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L. E. Crane  
Primary Patent Examiner  
Technology Center 1600